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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,462	08/14/2006	Yukiko Inamoto	2006_1261A	7229

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EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

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11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,462	INAMOTO ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 4-8 are pending.

Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 07/13/2009 is acknowledged. Applicant amended instant claim 4 and added new claims 7 and 8.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/2009 has been entered.

Applicants' arguments, filed 07/13/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102(b)

(New grounds of rejection necessitated by the amendment)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Inamoto et al (US 2003/0125308 an English equivalent of WO2001/047525, referenced in the instant IDS) as evidenced by Reller (US 4219548), (both references already of record)

Inamoto discloses external preparations having an excellent antipruritic activity acetylsalicylic acid as an active ingredients and a method of treating pruritis by using said external preparations [0001]. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, antifebrile activity and an antirheumatic activity being less on its side effects and superior in its safety [0006]. Inamoto also discloses that a new use of acetylsalicylic acid in the form of an external preparation, ointments for treating neuralgia and external preparations for treating skin injury and a transdermal administration system for treatment of thrombosis and prophylactic treatment of cancer has been illustrated in prior art [0008].

Inamoto discloses that the amount of acetyl salicylic acid in the external preparation depends on form of the preparation and is in the range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight. Inamoto additionally discloses that if the aspirin amount is greater than 80% by weight, it is impossible to maintain the physical property of an external preparation and when it is less than 0.05% by weight, there is not enough antipruritic activity and therefore the amount of more than 80% or less than 0.05% is not preferable [0014]. Inamoto teaches examples of diseases with itching for which the external preparation of his invention is

used as itching with skin diseases, such as atopic dermatitis, eczema, contact dermatitis etc.; senile pruritis; itching with metabolic diseases, such as hepatocirrhosis etc., itching with endocrine or dyshormonic disease such as diabetes; and itching with skin injury, such as cut, **wound after operation,** or burn [0015]. Inamoto further provides examples of external formulations comprising acetylsalicylic acid (examples 1-25, Tables 1-4, [0027-0030]). Inamoto finally teaches that the preparation as per his invention is applied to the lesion [0025].

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain. Since Inamoto teaches methods of administration of topical aspirin to lesions resulting from **Wounds after operation** Inamoto et al. anticipates instant claims 4-5 and 8 .

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al (US 2003/0125308 an English equivalent of WO2001/047525, referenced in the instant IDS) as evidenced by Reller (US 4219548), (both references already of record)

Inamoto discloses external preparations having an excellent antipruritic activity acetylsalicylic acid as an active ingredients and a method of treating pruritis by using said external preparations [0001]. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, antifebrile activity and an antirheumatic activity being

less on its side effects and superior in its safety [0006]. Inamoto also discloses that a new use of acetylsalicylic acid in the form of an external preparation, ointments for treating neuralgia and external preparations for treating skin injury and a transdermal administration system for treatment of thrombosis and prophylactic treatment of cancer has been illustrated in prior art [0008].

Inamoto discloses that the amount of acetyl salicylic acid in the external preparation depends on form of the preparation and is in the range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight. Inamoto additionally discloses that if the aspirin amount is greater than 80% by weight, it is impossible to maintain the physical property of an external preparation and when it is less than 0.05% by weight, there is not enough antipruritic activity and therefore the amount of more than 80% or less than 0.05% is not preferable [0014]. Inamoto teaches examples of diseases with itching for which the external preparation of his invention is used as itching with skin diseases, such as atopic dermatitis, eczema, contact dermatitis etc.; senile pruritis; itching with metabolic diseases, such as hepatocirrhosis etc., itching with endocrine or dyshormonic disease such as diabetes; and itching with skin injury, such as cut, **wound after operation,** or burn [0015]. Inamoto further provides examples of external formulations comprising acetylsalicylic acid (examples 1-25, Tables 1-4, [0027-0030]). Inamoto finally teaches that the preparation as per his invention is applied to the lesion [0025].

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is

useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Inamoto fails to teach the specific ranges of the acetylsalicilyic acid recited in instant claims 6-7. However, Inamoto's teachings that the external preparation of his invention comprises acetylsalicylic acid in the concentrations range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight, encompasses the instantly claimed ranges and thereby renders the instant claims obvious. Inamoto's additional teachings that having concentrations less than 0.05% or greater than 80% would not result in a stable composition provides an ordinarily skilled artisan additional motivation to further optimize the concentration to narrow down the dose range, thereby arriving at the instantly claimed concentrations. Additionally, It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizobuchi et al. (US 6268355 B 1) in view of Lee et al (Injury Vol.29,No 5, pages 345-347,1998)

Mizobuchi discloses a stable external preparation consisting essentially of acetylsalicylic acid and carriers (i.e., white vaseline, yellow vaseline, lanolin, purified bee wax, cetanol, steryl alcohol, stearic acid, hydrogenated oil, hydrocarbon gel, polyethylene glycol, liquid paraffin and squalane), wherein said preparation is formulated in the form of cataplasms, plasters, ointments, creams, external powders (col.3, line 30 to clol.4 lines 43 and examples 1-32) and the amount of aspirin as an active ingredient in an external preparation is 0.001 to 30% by weight per total amount, preferably 0.01 to 20% by weight, more preferably 0.05 to 15% by weight (column 2, lines 15-26 and 58-60;). Mizobuchi teaches that said composition is superior in stability and transdermal absorption from skin (column 2, lines 6-10 and 61-65; column 12, lines 65-67); and that said composition having anti-inflammatory antipyretic analgesic is useful in enhancing healing of skin injury (Figure 1 and Experiment 4). Mizubuchi discloses treatment of rats injured with the ointment of his invention comprising acetylsalicylic acid as the active ingredient (experiment 4, col.9, lines 25-46).

Mizobuchi does not specifically administer his inventive compounds to treat skin wounds selected from the group consisting of traumata, infectious diseases in surgery, postoperative wound, temperature impairment, chemical impairment, radiation injury etc,

However, Lee et al teaches that skin injuries occurs as a post-operative or post surgical procedure and involves injuries due to electrical current, thermal injury, chemical irritation or mechanical stress (page 346, under discussion to page 347, left col. 1st paragraph). As such, it would have been obvious to an ordinarily skilled artisan

to use the topical acetylsalicylic formulation taught by Mizobuchi in the treatment of postoperative wounds inflicted by either trauma, chemical, electrical or mechanical stress. An ordinarily skilled artisan would have a reasonable expectation of success that such a treatment would result in healing of the skin injury by motivation provided by Mizobuchi.

Response to applicant's arguments submitted on 07/13/2009

Applicant's arguments with respect to the previous rejection of the claims over namoto and Reller or Mizubuchi and Reller have been considered but are not persuasive in light of these new ground of rejection necessitated by Applicant's amendments to the claims. However, in the interest of a full prosecution history, the Examiner will address Applicant's arguments as they pertain to the present rejection

Examiner has considered Applicant's argument and does not find it persuasive.

Applicant argue that Inamoto et al and Mizubuchi et al does not disclose treatment of a skin wound selected from the group recited in instant claim 4. Examiner would like to point out that Inamoto et al explicitly teaches the topical administration of acetylsalicylic drugs to lesions or wounds after operation and therefore anticipates the instant claims. Mizubuchi et al teaches wounded rats with topical application of aspirin and teaches treatment of skin injuries. Skin injuries as taught by Lee et al results as a consequence of post-operative procedure or surgery and as such could very well be treated with the composition of Mizubuch who explicitly teaches healing of skin injuries with his acetylsalicylic formulation..

Conclusion

Claims 4-8 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614